

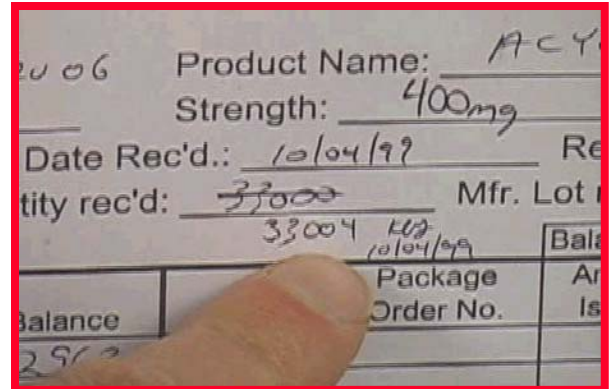
104: Documentation Medical Devices

(Course length: 2.5 Hours, 26 Graphics, 66 Pages \$750)

Purpose: To learn about our personal role and responsibilities in assuring CGMP compliance through complete and accurate completion of required documentation.

Objectives

1. Explain the rules for completing and correcting documents
2. Demonstrate proper documentation practices
3. Explain unacceptable documentation practices
4. State the other areas where documentation is important to our CGMP compliance



Topics and Activities:

1. Introduction and GMP opener activity
2. Regulations
3. Documentation rules and practices
 - ◆ Completing documentation
 - ◆ Correcting documentation
 - ◆ Error descriptions
 - ◆ Unacceptable documentation practices
 - ◆ Fraud and falsification policy
 - ◆ Activity: Short Term Memory
4. Double checking
 - ◆ Specific examples
 - ◆ Options
 - ◆ Activity: Documentation Contribution
5. Required documentation
 - ◆ Major equipment logs
 - ◆ Component, drug product, container, closures Labeling records
 - ◆ Production documentation
 - ◆ Production record review
 - ◆ Quality control
 - ◆ Specifications
 - ◆ Receiving, storing, and distribution records
 - ◆ Returned drug products or complaint records
6. Other required documentation
 - ◆ Quarantine system
 - ◆ Sampling
 - ◆ First In First Out
 - ◆ Charge-in of active ingredients
 - ◆ On line testing
 - ◆ Calculation of yield
 - ◆ Destruction of unused labeling
 - ◆ Work space cleaning
 - ◆ Maintenance
 - ◆ Training and education
 - ◆ Investigations
 - ◆ Validation
 - ◆ Internal audits
 - ◆ Calibration
 - ◆ Documentation retention
7. Wrap up
 - ◆ GMP quiz
 - ◆ Company problems
 - ◆ GMP closer activity
 - ◆ GMP wrap up activity
 - ◆ Change history
8. Glossary